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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,794	10/31/2003	Giovanni M. Pauletti	3715.17-1	1741

7590 12/21/2006

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,794	PAULETTI ET AL.	
	Examiner	Art Unit	
	Charlesworth Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-28 are currently pending in this application and are the subject of this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a polymer foam or film composition for delivery of pharmacologically effective agents topically to nasal, buccal, vaginal, labial or scrotal epithelium or through nasal, buccal, vaginal, labial or scrotal epithelium into a systemic circulation, said composition comprising at least one substrate polymer or a mixture of substrate polymers and a pharmacologically effective agent, classified in class 424, subclasses 430, 431, 434, and 435. If this Group is elected, then the below summarized Species Election is also required.

II. Claims 20 and 21, drawn to a device comprising a polymer foam or film composition of claims 1-18, said device suitable for delivery of therapeutically effective agents topically to a nasal, buccal, vaginal or labial cavity wherein said device is either coated with said composition or said composition is incorporated into said device, classified in class 514, subclasses 947, and 953+. If this Group is elected, then the below summarized Species Election is also required.

III. Claims 22-28, drawn to a method for topical or systemic delivery of drugs to or through nasal, buccal, vaginal, labial or scrotal epithelium, classified in class 424, subclass 430+. If this Group is elected, then the below summarized Species Election is also required.

Inventions I-III are related as product, apparatus, and process for use as the apparatus (invention II) and the process (invention III) as claimed can be used to practice the product (invention I).

Inventions I and II can be shown to be distinct if either or both of the following can be shown: (1) the apparatus/device for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different apparatus/device of using that product. See MPEP § 806.05(h). In the instant case, the apparatus for using the product as claimed can be used with a materially different product, for example, a food product.

Inventions I and III can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process or apparatus of using that product. See MPEP § 806.05(h). In the instant case, the process of using the product as claimed can be practiced with another materially different product. For example, invention III can be used to deliver an intravenous non-polymer containing drug formulation systemically.

Inventions II and III can be shown to be distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct because the inventions are either not capable of use together or can have a materially different design, mode of operation, function in view of their divergent subject matter. Specifically, Invention II is directed towards a device comprising a polymer foam or film composition suitable for delivery of therapeutically effective agents topically, while invention III can be used to deliver intravenous non-polymer containing drug formulations systemically.

Because inventions I-III are independent or distinct for the reasons given above coupled with the fact that a search is required for each group, restriction for examination purposes is proper. While Groups I-II can be identically classified under U.S. Patent Classification guidelines, to search them together would present an undue search burden on the Examiner due to the extensive databases of patent and non-patent literature that would have to be searched in view of the divergent subject matter encompassed by the different groups. Thus, Groups I-III have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Election of Species regarding Groups I-III

This application contains claims directed to more than one species of the generic

Inventions that would require an unduly extensive and burdensome search by the examiner if all the claimed species were examined together.

For example, the generic inventions encompass multiple species of pharmaceutical formulations; namely, a) foam, and b) film. These species possess different pharmaceutical properties. Thus, the species are independent or distinct because they exhibit different pharmaceutical characteristics. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect either a) foam, or b) film, for examination purposes.

In addition, if applicant elects invention II, then applicant is further required to:

1) elect a device wherein the foam or film is present as either a) coating, or

b) incorporated into the device (e.g. claims 20, and 21) and,

2) elect a single specific device from the below list for examination purpose; namely:

i) tampon, ii) tampon-like device, iii) ring, iv) sponge, v) pessary, vi) suppository, vii) pad, viii) strip, ix) cylinder, x) sphere, or xi) beads.

Additional Election of Species regarding Groups I-III

The generic inventions encompass multiple species of polymers. Each specie exhibit different pharmaceutical properties and therefore represent a different pharmaceutical agent. Thus, the species are independent or distinct because they exhibit different pharmaceutical properties. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect a single specific polymer for examination purposes e.g. hydropropyl methylcellulose, or gelatin, or alginic acid, or dimethyldiethoxysilane.

If applicant elects a composition comprising a combination of two or more polymer substrates (i.e. a mixture), then applicant is further required to specifically specify each constitutent polymer substrate for examination purposes.

Election of Species regarding Groups I-III

The generic inventions encompass multiple species of pharmacologically effective agents. Each specie therefore represent a different pharmacologic agent. For example, the generic inventions include the following species:

a) anti-osteoporotic, b) non-steroidal anti-inflammatory, c) calcium channel antagonists, d) local anesthetic, e) potassium channel antagonists, f) β-adrenergic agonist, g) vasodilator, h) cyclooxygenase inhibitor, i) anti-fungal, j) antiviral, k) antimicrobial, l) antiparasitic, m) anti-epileptic, n) anti-migraine, o) anti-HIV, p) anti-neurodegenerative, q) anti-psychotic, r) chemotherapeutic or antineoplastic, s) opioid analgesic agent, and t) biotechnology derived protein or peptide.

The species are independent or distinct because they exhibit different pharmacologic activities and have acquired a different status in the art. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect a single pharmacologically effective specie for examination purposes e.g. a) anti-osteoporotic, or b) non-steroidal anti-inflammatory, or calcium channel antagonist, or s) opioid analgesic agent etc.

In addition, applicant is further required to elect a single specific sub-specie from the above listed species for examination purposes.

For example, if applicant elects a) anti-osteoporotic, then applicant is further required to elect a single specific anti-osteoporotic drug for examination purposes e.g. alendronante.

If applicant elects b) nonsteroidal anti-inflammatory drug, then applicant is further required to elect a single specific nonsteroidal anti-inflammatory drug for examination purposes e.g. aspirin.

If applicant elects c) calcium channel antagonists, then applicant is further required to elect a single specific calcium channel antagonist for examination purposes e.g. diltiazem.

Election of Species regarding Groups I-III

The generic inventions encompass multiple species of topical drug delivery sites; namely, a) nasal, b) buccal, c) vaginal, d) labial, or e) scrotal epithelium. Each specie represents a distinct anatomical entity and exhibits different characteristics with respect to drug pharmacokinetics and pharmacodynamics as wells as having acquired a different status in the art. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect a single topical drug delivery site for examination purposes e.g. nasal, or buccal, or vaginal etc.

Election of Species regarding Groups I-III

The generic inventions also encompass multiple species of sub-compositions comprising the following:

1) penetration enhancer, 2) sorption promoter, 3) mucoadhesive agent, 4) hydrophilic or hydropholic release modifier, 5) or a mixture thereof, 6) additives or excipients .

Each specie composition exhibits different pharmaceutical properties. In view of the search burden that will be created by the divergent subject matter encompassed by the claims, applicant is required to elect a single composition wherein each constituent in the composition is specifically defined.

The above species are distinct as they exhibit different pharmaceutical and pharmacologic effects. The divergent subject matter, coupled with the fact that the species have acquired a different status in the art, creates a search burden on the examiner. In view of the undue search burden that will be created by the pharmaceutical agents and drug delivery sites encompassed by these claims, applicant is required to elect one single cell specie or subcompostion for examination purposes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 20, and 23 are considered generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

17 December 2006
CER

Ardin H. Marschel 12/18/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER